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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Part 178

[Docket No. 98F–0291]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the expanded safe use of sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in olefin polymers intended for use in contact with food. This action is in response to a petition filed by Asahi Denka Kogyo K.K.

DATES: The regulation is effective (*insert date of publication in the* **Federal Register**); written objections and requests for a hearing by (*insert date 30 days after date of publication in the* **Federal Register**).

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 7, 1998 (63 FR 25212), FDA announced that a food additive petition (FAP 8B4592) had been filed by Asahi Denka Kogyo K.K., 5–2–13, Shirahata, Urawa City, Saitama 336, Japan. The petition proposed to amend the food additive regulations in § 178.3295 *Clarifying agents for polymers* (21

CFR 178.3295) to provide for the expanded safe use of sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in olefin polymers intended for use in contact with food (21 CFR 177.1520).

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 178.3295 should be amended as set forth below.

FDA's review of this petition indicates that the additive may contain trace amounts of formaldehyde as an impurity. The potential carcinogenicity of formaldehyde was reviewed by the Cancer Assessment Committee (the Committee) of FDA's Center for Food Safety and Applied Nutrition. The Committee noted that for many years, formaldehyde has been known to be a carcinogen by the inhalation route, but the Committee concluded that these inhalation studies are not appropriate for assessing the potential carcinogenicity of formaldehyde in food. The Committee's conclusion was based on the fact that the route of administration (inhalation) is not relevant to the safety of formaldehyde residues in food and the fact that tumors were observed only locally at the portal of entry (nasal turbinates). In addition, the agency has received literature reports of two drinking water studies on formaldehyde: (1) A preliminary report of a carcinogenicity study purported to be positive by Soffritti et al. (1989), conducted in Bologna, Italy (Ref. 1); and (2) a negative study by Til et al. (1989), conducted in The Netherlands (Ref. 2). The Committee reviewed both studies and concluded, concerning the Soffritti study, "* * * that data reported were unreliable and could not be used in the assessment of the oral carcinogenicity of formaldehyde" (Ref. 3). This conclusion is based on a lack of critical detail in the study, questionable histopathological conclusions, and the use of unusual nomenclature to describe the tumors. Based on the Committee's evaluation, the agency has determined that there is no basis to conclude that formaldehyde is a carcinogen when ingested.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 8B4592 (63 FR 25212). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before (*insert date 30 days after date of publication in the* **Federal Register**), file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m and 4 p.m., Monday through Friday.

1. Soffritti, M., C. Maltoni, F. Maffei, and R. Biaggi, "Formaldehyde: An Experimental Multipotential Carcinogen," *Toxicology and Industrial Health*, vol. 5, No. 5, pp. 699–730, 1989.

2. Til, H. P., R. A. Woutersen, V. J. Feron, V. H. M. Hollanders, H. E. Falke, and J. J. Clary, "Two–Year Drinking Water Study of Formaldehyde in Rats," *Food Chemical Toxicology*, vol. 27, No. 2, pp. 77–87, 1989.

3. Memorandum of Conference concerning "Formaldehyde;" Meeting of the Cancer Assessment Committee, FDA, April 24, 1991, and March 4, 1993.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.3295 is amended in the table in the entry for "Sodium 2,2′-methylenebis (4,6-di-*tert*-butylphenyl)phosphate" by revising entry "2." under the heading "Limitations" to read as follows:

§ 178.3295 Clarifying agents for polymers.

* * * * *

Substances	Limitations
* * * *	* * *
Sodium 2,2'-methylenebis(4,6-di-*tert*-butylphenyl)phosphate (CAS Reg. No. 85209-91-2).	For use only: 1. * * * 2. As a clarifying agent at levels not exceeding 0.10 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, items 1.1(a) or 1.1(b) and of olefin polymers complying with § 177.1520(c) of this chapter, items 3.1(a), 3.1(b), 3.1(c), 3.2(a), or 3.2(b) (where the copolymers contain not less than 85 weight percent of the polymer units derived from polypropylene.) The finished polymers shall be used in contact with foods only under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter.
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Dated: December 1, 1998.

December 1, 1998.

William K. Hubbard
Associate Commissioner
for Policy Coordination

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